

5. 510(k) Summary

K090126

Submitter's Name: Fotona d.d.
Stegne 7
SI-1210 Ljubljana, Slovenia
Phone: +386 15009100
Fax: +386 5009 200

Contact Person: Stojan Trošt, QA&RA Manager
Phone: +386 1 5009 299
E-mail: stojan.trost@fotona.com

JUN 29 2009

Date: January 14, 2009

Device Name:

Trade name: Fotona XP Nd:YAG Laser System Family
Common name: Nd:YAG Surgical Laser
Classification name: Instruments, Surgical, Powered, Laser
79-GEX

DEVICE DESCRIPTION

The Fotona XP Laser System Family is based on the Nd:YAG (1064 nm) laser technology. There is one optical cavity containing the Nd:YAG crystal. The Nd:YAG laser is activated by means of the use of flashlamps. After the cavity, a red diode aiming beam is reflected onto a coaxial beam path using a beamsplitter assembly. The combined therapeutic and aiming beams are guided by an optical fiber delivery system to an optical handpiece. Optionally, the laser beams can be guided through fiber having SMA905 connector on the proximal end and bare fiber on distal end. The user activates laser emission by means of a footswitch.

The Nd:YAG (1064 nm) laser can be operated with variable pulse durations in the range of 0.1-50 msec, with repetition rates up to 100 Hz and laser pulse energies up to 10 J. Depending on the type of treatment, the user can choose between a PULSE mode user interface, and a QCW (Quasi-Continuous Wave) mode user interface. The laser operation is the same for both modes, the difference is only in the laser parameters that can be directly selected from the keyboard.

In the PULSE user interface mode the user can directly select the handpiece treatment spot size, laser fluence, pulse duration and pulse repetition rate. This mode is intended primarily for treatments at relatively small repetition rates, or in individual pulses, and at relatively high pulse energies. In this mode, a major expected treatment effect is the selective photothermolysis of target chromophores in soft tissue. For this reason it is more effective and safer that the energy is delivered to target chromophores in a relatively short time, in order not to cause damage to the surrounding tissue. Typically, the illuminated areas, or spotsizes are larger than 1 mm. A spotsize is determined by choosing and adjusting the handpiece. In this mode, the relevant and sufficient treatment parameters that have been accepted by the medical community are laser pulse energy, laser pulse fluence (energy over the spot-size area), pulse duration and pulse repetition rate. Recommended indications for use in this mode are:

- Removal of unwanted hair, for stable long term or permanent hair reduction and for treatment of PFB. The laser is indicated for all skin types, Fitzpatrick I-VI, including tanned skin

- Treatment of wrinkles
- Treatment of mild to moderate inflammatory acne vulgaris
- Photocoagulation and hemostasis of pigmented and vascular lesions, such as, but not limited to, port wine stains, hemaongiomae, warts, telangiectasiae, rosacea, venus lake, leg veins and spider veins

In the QCW user interface mode the user can directly select the laser pulse repetition rate, pulse width and the average laser power. This mode is intended primarily for treatments at relatively high repetition rates and small pulse energies. In this mode, a major expected treatment effect is incision, excision and coagulation of tissue via heating of the tissue in close contact with the fiber delivery of a known diameter (typically smaller than 1.0 mm), and over a time typically longer than 0.5 sec. For this reason, in this mode, average power, repetition rate (frequency) and pulse-width are the relevant and sufficient treatment parameters, accepted by the medical community, for performing various dental or surgical procedures. Recommended indications for use in this mode are:

- Surgical incision, excision, vaporization, ablation and coagulation of soft tissue. All soft tissue is included, striated and smooth tissue, muscle, cartilage, meniscus, mucous membrane, lymph vessels and nodes, organs and glands. It is further indicated for laser assisted lipolysis
- Endo Venous Laser Therapy of superficial incompetent tributary veins associated with varicose veins and varicosities
- Indications for use in dentistry:
 - Excisional and incisional biopsies
 - Excision and vaporization of herpes simplex I and II
 - Exposure of unerupted teeth
 - Fibroma removal
 - Frenectomy and frenotomy
 - Gingival troughing for crown impressions
 - Gingivectomy
 - Gingivoplasty
 - Gingival incision and excision
 - Hemostasis
 - Implant recovery
 - Incision and drainage of abscess
 - Laser assisted uvulopalaetoplasty (LAUP)
 - Operculectomy
 - Oral papillectomies
 - Pulpotomy and pulpotomy as an adjunct to root canal therapy
 - Reduction of denture hyperplasia
 - Reduction of gingival hypertrophy
 - Removal of filling material such as gutta percha or resin as adjunct treatment during root canal therapy
 - Removal of post-surgical granulations
 - Soft tissue crown lengthening
 - Sulcular debridement or soft tissue curettage (removal of diseased or inflamed soft tissue in the periodontal pocket to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment loss, and tooth mobility)
 - Tissue retraction for impression
 - Treatment of aphthous ulcers
 - Vestibuloplasty

STATEMENT OF SUBSTANTIAL EQUIVALENCE

Fotona believes that its Fotona XP Laser System Family is substantially equivalent to other legally-marketed predicate devices. The Fotona XP laser system family is comparable to the following predicate devices in terms of its indications for use, technical specifications, operating performance features, and general design features:

a) Fotona Fidelis III Er:YAG/ Nd:YAG Laser System (K070355), previously cleared for:

Nd:YAG laser (1064 nm wavelength) in dermatology and other surgical areas:

- Removal of unwanted hair, for stable long term or permanent hair reduction and for treatment of PFB. The laser is indicated for all skin types, Fitzpatrick I-VI, including tanned skin
- Photocoagulation and hemostasis of pigmented and vascular lesions, such as, but not limited to, port wine stains, hemaongioma, warts, telangiectasiae, rosacea, venus lake, leg veins and spider veins
- Treatment of wrinkles
- Treatment of mild to moderate inflammatory acne vulgaris

Nd:YAG laser (1064 nm wavelength) in dentistry:

- Excisional and incisional biopsies
- Excision and vaporization of herpes simplex I and II
- Exposure of unerupted teeth
- Fibroma removal
- Frenectomy and frenotomy
- Gingival troughing for crown impressions
- Gingivectomy
- Gingivoplasty
- Gingival incision and excision
- Hemostasis
- Implant recovery
- Incision and drainage of abscess
- Laser assisted uvulopalatoplasty (LAUP)
- Operculectomy
- Oral papillectomies
- Pulpotomy and pulpotomy as an adjunct to root canal therapy
- Reduction of denture hyperplasia
- Reduction of gingival hypertrophy
- Removal of filling material such as gutta percha or resin as adjunct treatment during root canal therapy
- Removal of post-surgical granulations
- Soft tissue crown lengthening
- Sulcular debridement or soft tissue curettage (removal of diseased or inflamed soft tissue in the periodontal pocket to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment loss, and tooth mobility)
- Tissue retraction for impression
- Treatment of aphthous ulcers
- Vestibuloplasty

b) Millennium Periolase Nd:YAG Laser System (K030290) previously cleared for:

- Ablation, incision, excision, vaporization and coagulation of soft tissues using a contact fiber optic delivery system

- c) **Cooltouch Nd:YAG Laser System (K061618), Dornier Medilas D family (K073427) and Diomed Delta family of laser systems (K051996) previously cleared for:**
 - Endo Venous Laser Therapy of superficial incompetent tributary veins associated with varicose veins and varicosities
- d) **Cynosure SmartLipo and SmartLipo MPX Nd:YAG laser system (K062321, K080121), and Syneron LipoLite (eLipo) (K073715) previously cleared for:**
 - Surgical incision, excision, vaporization, ablation and coagulation of soft tissue. All soft tissue is included, striated and smooth tissue, muscle, cartilage, meniscus, mucous membrane, lymph vessels and nodes, organs and glands. It is further indicated for laser assisted lipolysis
- e) **Candela GentleYAG Family of Laser Systems (K033172) previously cleared for:**
 - Removal of unwanted hair, for stable long term or permanent hair reduction and for treatment of PFB. The laser is indicated for all skin types, Fitzpatrick I-VI, including tanned skin
 - Photocoagulation and hemostasis of pigmented and vascular lesions, such as, but not limited to, port wine stains, hemaongioma, warts, telangiectasiae, rosacea, venus lake, leg veins and spider veins
 - Coagulation and hemostasis of soft tissue
 - Treatment of wrinkles
- f) **Cooltouch Nd:YAG Laser System (K040131) and Laserscope Gemini Laser System (K034011) previously cleared for:**
 - Treatment of mild to moderate inflammatory acne vulgaris

Details are provided in the Substantial Equivalence Discussion Section of this submission.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JUN 29 2009

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Fotona D.D.
% Stojan Trošt
QA/RA Manager
Stegne 7, 1210 Ljubljana
Slovenia

Re: K090126

Trade/Device Name: Fotona XP Nd:YAG Laser System Family

Regulation Number: 21 CFR 878.4810

Regulation Name: Laser surgical instrument for use in general and plastic surgery
and in dermatology

Regulatory Class: II

Product Code: GEX

Dated: June 16, 2009

Received: June 19, 2009

Dear Stojan Trošt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

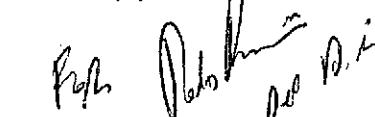
Page 2 - Stojan Trošť

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/cdrh/mdr/> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use Statement

510(k) Number (if known):

Device Name: **Fotona XP Nd:YAG Laser System Family**

Indications For Use:

Nd:YAG laser (1064 nm wavelength) in dermatology and other surgical areas:

- Surgical incision, excision, vaporization, ablation and coagulation of soft tissue. All soft tissue is included, striated and smooth tissue, muscle, cartilage, meniscus, mucous membrane, lymph vessels and nodes, organs and glands. It is further indicated for laser assisted lipolysis
- Removal of unwanted hair, for stable long term or permanent hair reduction and for treatment of PFB. The laser is indicated for all skin types, Fitzpatrick I-VI, including tanned skin
- Treatment of wrinkles
- Treatment of mild to moderate inflammatory acne vulgaris
- Photocoagulation and hemostasis of pigmented and vascular lesions, such as, but not limited to, port wine stains, hemaongioma, warts, telangiectasiae, rosacea, venus lake, leg veins and spider veins
- Endo Venous Laser Therapy of superficial incompetent tributary veins associated with varicose veins and varicosities

Nd:YAG laser (1064 nm wavelength) in dentistry:

- Excisional and incisional biopsies
- Excision and vaporization of herpes simplex I and II
- Exposure of unerupted teeth
- Fibroma removal
- Frenectomy and frenotomy
- Gingival troughing for crown impressions
- Gingivectomy
- Gingivoplasty
- Gingival incision and excision
- Hemostasis
- Implant recovery
- Incision and drainage of abscess
- Laser assisted uvulopalatoplasty (LAUP)
- Operculectomy
- Oral papillectomies
- Pulpotomy and pulpotomy as an adjunct to root canal therapy
- Reduction of denture hyperplasia
- Reduction of gingival hypertrophy
- Removal of filling material such as gutta percha or resin as adjunct treatment during root canal therapy
- Removal of post-surgical granulations
- Soft tissue crown lengthening
- Sulcular debridement or soft tissue curettage (removal of diseased or inflamed soft tissue in the periodontal pocket to improve clinical indices including gingival index, gingival bleeding index,

Neil R. Ophir, Sr. M.D.
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K 090126

probe depth, attachment loss, and tooth mobility)

- Tissue retraction for impression
- Treatment of aphtous ulcers
- Vestibuloplasty

Prescription Use: X
(21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use: _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark B. Ogle, Sr. mba
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K090126